



# **Egyptian Herbal Monograph**

**Volume 3**

**Medicinal Plants used in Egypt**

**Egyptian Drug Authority (EDA)**

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Primula veris* L.

زَهْرَةُ الرَّبِيعِ

### 1. Names & Synonyms (1)

*Primula veris* L.

**Family:** Primulaceae

**Syns.:** *Primula officinalis* L. Hill.

**Arabic:** Zahr El-hakl زهر الحقل, Zahrat El-rabee' زهرة الربيع

**English name:** Cowslip (2-4), Primula (4).

### 2. Parts used for medicinal purpose

Dried Flowers and Roots (2-4).

### 3. Major chemical constituents

#### Flowers:

- Phenolic compounds: including flavonoids as rutin and isorhamnetin 3-*O*-rutinoside (5), hyperoside catechin, astragalín and catechin (6).

#### Leaves:

- Kaempferol 3-*O*-rutinoside-7-*O*-rhamnoside, rutin, vitamin C (5).

#### Roots:

- Triterpene saponins (6): Primula saponins I and II, priverosaponin B22-acetate (4, 5).
- Phenolic glycosides: primverin and primulaverin (4, 6).

### 4. Medicinal Uses (Indications)

Expectorant in cough associated with cold (4).

## 5. Herbal preparations correlated to medicinal use (4)

### 1. Comminuted herbal substance as herbal tea for oral use

1.1 Roots.

1.2 Flowers.

### 2. Dry extract (DER 3-9:1), extraction solvent ethanol 40-50 % v/v (Roots).

### 3. Liquid extract

3.1 Extraction solvent ethanol, 70 % v/v (Roots), (DER 1:1).

3.2 Extraction solvent ethanol 70% v/v (Roots), (DER 1:2.0-2.5).

3.3 Extraction solvent ethanol 25% v/v (flowers), (DER 1:1).

### 4. Tincture (1:5), extraction solvent ethanol 70 % v/v (Roots).

### 5. Soft extract (Roots)

1.1 Extraction solvent water (DER 5-10:1).

5.2 Extraction solvent ethanol 20-55% v/v, (DER 1-4:1).

Herbal preparations (2-5) are in pharmaceutical dosage forms. The pharmaceutical form should be described by the pharmacopoeia full standard term.

## 6. Posology and method of administration correlated to medicinal use (4)

### Preparation 1

#### Preparations 1.1

**Adolescents, adults, elderly:** 0.2 – 0.5 g in 150 ml of boiling water as an herbal infusion, 3 times daily.

#### Preparation 1.2

**Adolescents, adults, elderly:** 1 g in 150 ml of boiling water as an herbal infusion, 3 times daily.

### Preparation 2

#### Adolescents, adults, elderly:

- Single dose: 0.1 – 0.2 g, 3 times daily.
- Single dose equivalent to 0.2 – 0.5 g herbal substance, 3 times daily.

### Preparation 3

#### Preparations 3.1

**Adolescents, adults, elderly:** Single dose: 0.5 g, 3 times daily.

#### Preparations 3.2

**Adolescents, adults, elderly:** Single dose: 0.6 g, 4 times daily.

**Children between 4-12 years of age:** Single dose 0.33 g, 3 times daily.

#### Preparations 3.3

Single dose: 1 - 3 ml, up to 3 times daily, Maximum daily dose 6 ml (2, 3).



#### Preparation 4

**Adolescents, adults, elderly:** Single dose: 0.5 – 1 g, 3 times daily.

**Children between 4-12 years of age:** Single dose 0.3 – 0.5 ml, 3 times daily.

#### Preparation 5

##### Preparations 5.1 and 5.2

**Adolescents, adults, elderly:** Single dose equivalent to 0.2 – 0.5 g herbal substance, 3 times daily.

##### Preparation 5.2

**Children between 6 - 12 years of age:** Single dose 0.12 g, 3-4 times daily.

**Children between 4 - 6 years of age:** Single dose 0.12 g, 3 times daily.

#### Duration of use

If the symptoms persist longer than 1 week, a doctor or a pharmacist should be consulted.

**Method of administration:** Oral use.

## 7. Contraindications

Hypersensitivity to the active substance or to other Primula species (4).

## 8. Special warnings and precautions for use (4)

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- Preparations **1, 2, 3.1, 3.3 and 5.2:** The use in children under 12 years of age is not recommended.
- Preparations **3.2, 4 and 5.2:** The use in children under 4 years of age is not recommended.
- Caution is recommended in patients with gastritis or gastric ulcer.
- If dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.

## 9. Interactions with other medicinal products and other forms of interaction (2)

- **Antihypertensives, diuretics:** Cowslip may increase the effect of antihypertensives, diuretics.
- **CNS depressants:** Cowslip may increase the effect of antianxiety agents and sedatives/hypnotics; concurrent use should be avoided.



- **Lab Test: AST, ALT, alkaline phosphatase:** Cowslip may increase these levels.

#### **10. Fertility, pregnancy and lactation (4)**

- Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
- No fertility data available.

#### **11. Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed.

#### **12. Undesirable effects (4)**

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Allergic reactions may occur.

#### **13. Overdose (4)**

Overdose may lead to stomach upset, vomiting or diarrhoea.

#### **14. Relevant biological activities**

Not required as per Egyptian guidelines for registration of herbal medicines.

#### **15. Additional Information**

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#### **16. Date of last revision**

06/09/2022.

## References

1	<a href="http://www.theplantlist.org">http://www.theplantlist.org</a> .
2	Skidmore-Roth, L. (2010). Mosby's Handbook of Herbs & Natural Supplements. 4 <sup>th</sup> ed. ISBN 9780323057417.
3	Barnes, J., Anderson, L. A. and Phillipson, J. D. (2007). Herbal Medicines, 3 <sup>rd</sup> edition. Published by the Pharmaceutical Press. ISBN 978 0 85369 623 0.
4	European Union Herbal Monograph on <i>Primula veris</i> L. and/or <i>Primula elatior</i> L. Hill, Radix (2012). EMA/HMPC/104095/2012. Committee on Herbal Medicinal Products (HMPC).
5	Tarapatskyy, M., Gumienna, A., Sowa, P., Kapusta, I. and Puchalski, C. (2021). Bioactive phenolic compounds from <i>Primula veris</i> L.: Influence of the extraction conditions and purification. <i>Molecules</i> , <b>26</b> (4), 997.
6	Katarzyna, B., Jarosław, L. P., Małgorzata, M., Olga, K., Izabela, S. S. and Zenon, W. (2017). Phenolics in <i>Primula veris</i> L. and <i>P. elatior</i> (L.) Hill raw materials. <i>International Journal of Analytical Chemistry</i> , Article ID 2871579. <a href="https://doi.org/10.1155/2017/2871579">https://doi.org/10.1155/2017/2871579</a> .